

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1256R3

Serial No.

09/209,023

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

MAR 15 1999

Applicant

Paton et al.

Filing Date

10 Dec 1998

Group

1643

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
(JN)	1	5,359,046	25.10.94	Capon et al.			
(JN)	2	5,578,482	26.11.96	Lippman et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
(JN)	3	WO 89/06692	27.07.89	PCT				
(JN)	4	WO 94/00136	06.01.94	PCT				
(JN)	5	WO 94/22478	13.10.94	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

(JN)	6	Arteaga et al., "p185C-erbB-2 signaling enhances cisplatin-induced cytotoxicity in human breast carcinoma cells: association between an oncogenic receptor tyrosine kinase and drug-induced DNA repair" <u>Cancer Research</u> 54(14):3758-3765 (Jul 15, 1994)					
(JN)	7	Bacus et al., "Differentiation of cultured human breast cancer cells (AU-565 and MCF-7) associated with loss of cell surface HER-2/neu antigen" <u>Molecular Carcinogenesis</u> 3(6):350-362 (1990)					
(JN)	8	Bacus et al., "Tumor-inhibitory monoclonal antibodies to the HER-2/Neu receptor induce differentiation of human breast cancer cells" <u>Cancer Research</u> 52(9):2580-2589 (May 1, 1992)					
(JN)	9	Baselga et al., "Anti HER2 Humanized Monoclonal Antibody (Mab) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts" <u>Proceedings of ASCO-13th Annual Meeting</u> (Abstract #53), Dallas, TX 13:63 (Mar 1994)					
(JN)	10	Baselga et al., "HER2 overexpression and paclitaxel sensitivity in breast cancer: therapeutic implications" <u>Oncology</u> 11(3 Suppl 2):43-48 (Mar 1997)					
(JN)	11	Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185HER2 Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer" <u>J. Clin. Oncol.</u> 14(3):737-744 (1996)					
(JN)	12	Carter et al., "Humanization of an anti-p185HER2 antibody for human cancer therapy" <u>Proc. Natl. Acad. Sci.</u> 89:4285-4289 (1992)					
(JN)	13	D'souza et al., "Overexpression of ERBB2 in human mammary epithelial cells signals inhibition of transcription of the E-cadherin gene" <u>Proc. Natl. Acad. Sci. USA</u> 91(15):7202-7206 (Jul 19, 1994)					
(JN)	14	DiFiore et al., "erbB-2 is a potent oncogene when overexpressed in NIH/3T3 cells" <u>Science</u> 237(4811):178-182 (Jul 10, 1987)					
(JN)	15	Drebin et al., "Down-Modulation of and Oncogene Protein Product an Reversion of the Transformed Phenotype by Monoclonal Antibodies" <u>Cell</u> 41(3):695-706 (1985)					
(JN)	16	Drebin et al., "Inhibition of tumor growth by a monoclonal antibody reactive with an oncogene-encoded tumor antigen" <u>Proc. Natl. Acad. Sci.</u> 83:9129-9133 (1986)					
(JN)	17	Drebin et al., "Monoclonal antibodies reactive with distinct domains of the neu oncogene-encoded p185 molecule exert synergistic anti-tumor effects in vivo" <u>Oncogene</u> 2:273-277 (1988)					
(JN)	18	Drebin et al., "Monoclonal Antibodies Specific for the neu Oncogene Product Directly Mediate Anti-tumor Effects In Vivo" <u>Oncogene</u> 2(4):387-394 (1988)					
(JN)	19	Fendly et al., "Characterization of Murine Monoclonal Antibodies Reactive to Either the Human Epidermal Growth Factor Receptor or HER2/neu Gene Product" <u>Cancer Research</u> 50:1550-1558 (March 1, 1990)					

Examiner

Jennifer Nichols nee Hunt

Date Considered

1/03/2000

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1256R3	Serial No. 09/209,023
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Paton et al.	
				Filing Date 10 Dec 1998	Group 1643
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
(jn)	20	Fleiss, JL <u>Statistical Methods for Rates and Proportions</u> , 2nd edition, New York, NY:Wiley pps. 13-17 (1981)			
(jn)	21	Green et al., "Preclinical Evaluation of WR-151327: An Orally Active Chemotherapy Protector" <u>Cancer Research</u> 54(3):738-741 (Feb 1, 1994)			
(jn)	22	Guy et al., "Expression of the neu protooncogene in the mammary epithelium of transgenic mice induces metastatic disease" <u>Proc. Natl. Acad. Sci. USA</u> 89(22):10578-10582 (Nov 15, 1992)			
(jn)	23	Hancock et al., "A Monoclonal Antibody Against the c-erbB-2 Protein Enhances the Cytotoxicity of cis-Diamminedichloroplatinum Against Human Breast and Ovarian Tumor Cell Lines" <u>Cancer Research</u> 51:4575-4580 (September 1, 1991)			
(jn)	24	Harwerth et al., "Monoclonal antibodies against the extracellular domain of the erbB-2 receptor function as partial ligand agonists" <u>Journal of Biological Chemistry</u> 267(21):15160-15167 (Jul 1992)			
(jn)	25	Hudziak et al., "Increased expression of the putative growth factor receptor p185HER2 causes transformation and tumorigenesis of NIH 3T3 cells" <u>Proc. Natl. Acad. Sci.</u> 84:7159-7163 (1987)			
(jn)	26	Hudziak et al., "p185HER2 Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor" <u>Molecular & Cellular Biology</u> 9(3):1165-1172 (1989)			
(jn)	27	Hynes and Stern, "The biology of erbB-2/neu/HER-2 and its role in cancer" <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)			
(jn)	28	Kasprzyk et al., "Therapy of an animal model of human gastric cancer using a combination of anti-erbB-2 monoclonal antibodies" <u>Cancer Research</u> 52(10):2771-2776 (May 15, 1992)			
(jn)	29	Kotts et al., "Differential growth inhibition of human carcinoma cells exposed to monoclonal antibodies directed against the extracellular domain of the HER2/ERBB2 protooncogene" <u>In Vitro</u> (Abstract #176) 26(3):59A (1990)			
(jn)	30	Kumar et al., "Regulation of phosphorylation of the c-erbB-2/HER2 gene product by a monoclonal antibody and serum growth factor(s) in human mammary carcinoma cells" <u>Molecular & Cellular Biology</u> 11(2):979-986 (Feb 1991)			
(jn)	31	Lewis et al., "Differential Responses of Human Tumor Cell Lines to Anti-p185HER2 Monoclonal Antibodies" <u>Cancer Immunol. Immunother.</u> 37:255-263 (1993)			
(jn)	32	Maier et al., "Requirements for the internalization of a murine monoclonal antibody directed against the HER-2/neu gene product c-erbB-2" <u>Cancer Research</u> 51(19):5361-5369 (Oct 1, 1991)			
(jn)	33	McKenzie et al., "Generation and characterization of monoclonal antibodies specific for the human neu oncogene product, p185" <u>Oncogene</u> 4:543-548 (1989)			
(jn)	34	Myers et al., "Biological Effects of Monoclonal Antireceptor Antibodies Reactive with neu Oncogene Product, p185neu" <u>Methods in Enzymology</u> 198:277-290 (1991)			
(jn)	35	Norton, L, "Evolving concepts in the systemic drug therapy of breast cancer" <u>Seminars in Oncology</u> 24(4 Suppl 10):S10-3-S10-10 (Aug 1997)			
(jn)	36	Pietras et al., "Antibody to HER-2/neu Receptor Blocks DNA Repair After Cisplatin in Human Breast and Ovarian Cancer Cells" <u>Oncogene</u> 9:1829-1838 (1994)			
(jn)	37	Ravdin and Chamness, "The c-erbB-2 proto-oncogene as a prognostic and predictive marker in breast cancer: a paradigm for the development of other macromolecular markers--a review" <u>Gene</u> 159(1):19-27 (Jun 14, 1995)			
(jn)	38	Sarup, "Characterization of an Anti-P185HER2 Monoclonal Antibody that Stimulates Receptor Function and Inhibits Tumor Cell Growth" <u>Growth Regulation</u> 1:72-82 (1991)			
(jn)	39	Scott et al., "p185HER2 signal transduction in breast cancer cells" <u>Journal of Biological Chemistry</u> 266(22):14300-14305 (Aug 5, 1991)			
Examiner		Jennifer Nichols nee Hunt		Date Considered 1/03/2000	
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1256R3	Serial No. 09/209,023
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Paton et al.	
				Filing Date 10 Dec 1998	Group 1643
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
40	Selfert et al., "Dexrazoxane in the prevention of doxorubicin-induced cardiotoxicity" <u>Annals of Pharmacotherapy</u> 28(9):1063-1072 (Sep 1994)				
41	Shawver et al., "Ligand-like effects induced by anti-c-erbB-2 antibodies do not correlate with and are not required for growth inhibition of human carcinoma cells" <u>Cancer Research</u> 54(5):1367-1373 (Mar 1, 1994)				
42	Shepard et al., "Monoclonal Antibody Therapy of Human Cancer: Taking the HER2 Protooncogene to the Clinic" <u>J. Clin. Immunol.</u> 11(3):117-127 (1991)				
43	Singal and Iliskovic, "Doxorubicin-induced cardiomyopathy" <u>New England J. of Medicine</u> 339(13):900-905 (Sep 24, 1998)				
44	Singal et al., "Combination therapy with probucol prevents adriamycin-induced cardiomyopathy" <u>Journal of Molecular & Cellular Cardiology</u> 27(4):1055-1063 (Apr 1995)				
45	Slamon et al., "Human Breast Cancer: Correlation of Relapse and Survival with Amplification of the HER-2/neu Oncogene" <u>Science</u> 235:177-182 (1987)				
46	Slamon, et al., "Studies of the HER-2/neu Proto-oncogene in Human Breast and Ovarian Cancer" <u>Science</u> 244:707-712 (May 1989)				
47	Slivkowski et al., "Coexpression of erbB2 and erbB3 proteins reconstitutes a high affinity receptor for heregulin" <u>Journal of Biological Chemistry</u> 269(20):14661-14665 (1994)				
48	Stancovski et al., "Mechanistic aspects of the opposing effects of monoclonal antibodies to the ERBB2 receptor on tumor growth" <u>Proc. Natl. Acad. Sci. USA</u> 88(19):8691-8695 (Oct 1, 1991)				
49	Tagliabue et al., "Selection of monoclonal antibodies which induce internalization and phosphorylation of p185 ^{HER2} and growth inhibition of cells with HER2/NEU gene amplification" <u>International Journal of Cancer</u> 47(6):933-937 (Apr 1, 1991)				
50	Vitetta et al., "Monoclonal antibodies as agonists: an expanded role for their use in cancer therapy" <u>Cancer Research</u> 54(20):5301-5309 (Oct 15, 1994)				
51	Xu et al., "Antibody-induced growth inhibition is mediated through immunochemically and functionally distinct epitopes on the extracellular domain of the c-erbB-2 (HER- 2/neu) gene product p185" <u>International Journal of Cancer</u> 53(3):401-408 (Feb 1, 1993)				
Examiner	Jennifer Nichols nee Hunt	Date Considered	1/03/2000		

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Case Docket No.
P1256R3

Serial No.
09/209,023


LIST OF DISCLOSURES CITED BY ~~APPLICANT~~
(Use several sheets if necessary)

Applicant
Paton et al.

Filing Date
10 Dec 1998

Group
1643

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	5,677,171	14.10.97	Hudziak et al.			
	2	5,705,157	06.01.98	Greene			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
AM	3	WO 97/20858	12.06.97	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

[illegible]

Examiner

Jennifer Nichols nee Hunt

Date Considered 1/03/2000

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.